IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9201

Bartle, J. January 30, 2014

Cynthia L. Elliott ("Ms. Elliott" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

Under the Settlement Agreement, only eligible claimants are entitled to Matrix Benefits. Generally, a claimant is considered eligible for Matrix Benefits if he or she is diagnosed with mild or greater aortic and/or mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug

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2. (...continued)
medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

use and the end of the Screening Period.[3] See Settlement Agreement § IV.B.1.a.

In January, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, George P. Hanna, M.D., F.A.C.C. Based on an echocardiogram dated October 24, 2002, Dr. Hanna attested in Part II of claimant's Green Form that Ms. Elliott suffered from mild mitral regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™.[4] Based on such findings, claimant would be entitled to Matrix B-1,[5] Level III benefits in the amount of $152,118.[6]

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3. The Screening Period ended on January 3, 2003 for echocardiograms performed outside of the Trust's Screening Program and on July 3, 2003 for echocardiograms performed in the Trust's Screening Program. See Settlement Agreement § I.49.

4. Dr. Hanna also attested that claimant suffered from moderate aortic regurgitation, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class I symptoms. These conditions are not at issue in this claim.

5. The Settlement Agreement requires the payment of reduced Matrix Benefits for a claim based on damage to the mitral valve if the Diet Drug Recipient was diagnosed with mild mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period. See Settlement Agreement § IV.B.2.d.(2)(a). Although claimant requested Matrix A-1, Level II benefits, she did not contest the Trust's determination that her claim is payable, if at all, on Matrix B-1, Level III.

6. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin®

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In the report of claimant's echocardiogram, Dr. Hanna stated that claimant had mild mitral regurgitation. Dr. Hanna, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, mild mitral regurgitation is defined as "(1) either the RJA/LAA ratio is more than five percent (5%) or the mitral regurgitation jet height is greater than 1 cm from the valve orifice, and (2) the RJA/LAA ratio is less than twenty percent (20%)." Settlement Agreement § I.38.

In January, 2012, the Trust forwarded the claim for review by Noyan Gokce, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Gokce determined that there was no reasonable medical basis for the attesting physician's representation that Ms. Elliott had at least mild mitral regurgitation between the commencement of Diet Drug use and the end of the Screening Period. Specifically, Dr. Gokce explained, "The study is technically limited. There was no evidence of any sustained or discernable jet of mitral regurgitation in any of the views."[7]

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6. (...continued)
and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a). As the Trust concedes that Ms. Elliott underwent surgery to repair her mitral valve, the only issue is whether she is eligible for benefits.

7. Dr. Gokce also determined that there was no reasonable medical basis for the attesting physician's finding that
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Based on Dr. Gokce's finding that there was no reasonable medical basis for finding that Ms. Elliott had at least mild mitral regurgitation between the commencement of Diet Drug use and the end of the Screening Period, the Trust issued a post-audit determination denying Ms. Elliott's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[8] In contest, Ms. Elliott argued that the reports of her August 30, 2000 and October 24, 2002 echocardiograms indicate at least mild mitral regurgitation. According to claimant, the auditing cardiologist substituted his opinion for that of her treating cardiologist.

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist. Dr. Gokce submitted a declaration in which he again concluded

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7. (...continued)
Ms. Elliott did not have rheumatic mitral valves. Under the Settlement Agreement, the presence of a rheumatic mitral valve requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)e). Given our disposition with respect to the level of claimant's mitral regurgitation, we need not address this issue.

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Elliott's claim.

that there was no reasonable medical basis for the attesting physician's representation that Ms. Elliott had mild mitral regurgitation. Specifically, Dr. Gokce explained, in pertinent part:

> 8. I was asked to determine whether there is a reasonable medical basis (1) for the Green Form representation that claimant had mild mitral regurgitation and (2) for Claimant's assertion in Contest, that she had mild mitral regurgitation in between Diet Drug use and the close of the Screening Period (January 3, 2003), based upon studies dated 8/30/00 and 10/24/02.
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> 9. In accordance with the Trust's request, I reviewed the Claim and Claimant's Contest. I reviewed the 10/24/02 echocardiogram of attestation, the 6/19/01 study, and the report of the study dated 8/30/00. (The 8/30/00 study was not available for review.)
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> 10. I confirm my finding at audit that there is no reasonable medical basis for the Attesting Physician's Green Form representation that Claimant had mild mitral regurgitation. As I noted at the time of audit, the October 24, 2002 echocardiogram of attestation is of very poor quality, and there are no findings by Color Doppler assessment that would qualify for even mild mitral regurgitation, as defined by audit criteria, in any views. There is no reasonable medical basis to conclude that mild mitral regurgitation is present on this study which is technically poor quality.
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> 11. I also find, after review of Claimant's medical records at Contest, including the 10/24/02 echocardiogram of attestation, the 6/19/01 study, and the

> 8/30/00 echo report, that there is no reasonable medical basis to conclude that Claimant had mild mitral regurgitation in between Diet Drug use and the close of the Screening Period (January 3, 2003). The June 16, 2001 [sic] study is of very poor quality. By Color Doppler, there is nothing that that [sic] qualifies as mild mitral regurgitation. There is no reasonable medical basis to conclude that mild mitral regurgitation is present on the June 16, 2001 [sic] study.

The Trust then issued a final post-audit determination, again denying Ms. Elliott's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why his claim should be paid. On July 9, 2012, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8904 (July 9, 2012).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust informed the Special Master by letter dated November 15, 2012 that it did not intend to submit a reply. Under the Audit Rules, it is within the Special Master's

discretion to appoint a Technical Advisor[9] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for finding that Ms. Elliott suffered from at least mild mitral regurgitation between the commencement of Diet Drug use and the end of the Screening Period. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Elliott reasserts that there is a reasonable medical basis for Dr. Hanna's representation that she had mild mitral regurgitation. According to claimant, she received a letter from the Trust confirming that she was FDA Positive based on an echocardiogram performed in the Screening Program by Dr. Hanna.[10] In addition, claimant notes that she received benefits pursuant to the Seventh Amendment because she had aortic and mitral regurgitation. Claimant also contends that she would have obtained another echocardiogram if the Trust had timely informed her that the October 24, 2002 echocardiogram was of poor quality. Finally, claimant asserts that two physicians can read the same study and come to different conclusions.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiograms and concluded that there was no reasonable medical basis for finding that Ms. Elliott had mild mitral regurgitation prior to the end of the Screening Period. Specifically, Dr. Vigilante explained, in pertinent part:

> I reviewed the tape of the Claimant's echocardiogram of attestation. The Claimant's name and date of October 24, 2002

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10. FDA Positive is defined as "mild or greater regurgitation of the aortic valve and/or moderate or greater regurgitation of the mitral valve." Settlement Agreement § I.22.

> were documented on the study.... This was a poor quality study. There was poor ultrasound transmission with decreased endocardial definition. There was increased echo gain. The Nyquist was appropriately set at 57 cm/sec at 24 cm of depth in the apical four chamber view. In addition, this was an incomplete study as there was no evaluation of the aortic regurgitant jet in the parasternal long-axis view and there was no evaluation of mitral regurgitation in the apical two chamber view.
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> .... Visually, mitral regurgitation was not seen on color flow evaluation in the apical four chamber view. I digitized the cardiac cycles in the apical four chamber view during color flow evaluation. In a frame-by-frame evaluation, there was no sustained jet of mitral regurgitation seen on this study. Pulse wave Doppler of this study failed to demonstrate an envelope of mitral regurgitation....
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> ....
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> I also reviewed the tape of the Claimant's echocardiogram of June 19, 2001.... This was a poor quality study with poor ultrasound transmission and decreased endocardial definition. In addition, there was no evaluation of mitral regurgitation in the apical two chamber view.
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> .... Evaluation in the apical four chamber view failed to demonstrate a sustained jet of mitral regurgitation. On continuous wave Doppler, a faint jet of [mitral regurgitation] was noted. However, there was no RJA that could be possibly planimetered on this study....

After reviewing the entire Show Cause Record, we find the claimant's arguments are without merit. As an initial matter, claimant does not adequately rebut the findings of the

auditing cardiologist or the Technical Advisor. Dr. Gokce reviewed claimant's June 19, 2001 and October 24, 2002 echocardiograms and determined that there was no evidence of mild mitral regurgitation. Although claimant contested the findings, she did not identify any error in his analysis.[11] In addition, Dr. Vigilante reviewed claimant's June 19, 2001 and October 24, 2002 echocardiograms and concluded that "these two echocardiograms do not show a sustained jet of mitral regurgitation in the apical four chamber view."[12] Mere disagreement with the auditing cardiologist and the Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

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11. We disagree with claimant that she is entitled to benefits simply because the Trust purportedly informed her she was FDA Positive and she received benefits pursuant to the Seventh Amendment. As an initial matter, a letter from the Trust informing claimant she is FDA Positive is irrelevant to whether she has established a reasonable medical basis for her Seventh Amendment Matrix Compensation Claim as all such claims must be submitted to audit. See Mem. in Supp. of PTO No. 2662, at 13 (Nov. 26, 2002). Moreover, the Seventh Amendment specifically provides that the payment of Seventh Amendment benefits "shall have no preclusive or precedential effect of any kind on the Trust in the administration of claims for ... Seventh Amendment Matrix Compensation Benefits." Seventh Amendment § IX.E. In addition, claimant's contention that the quality of her echocardiograms is the basis for her inability to establish eligibility for Matrix Benefits is misplaced; neither the auditing cardiologist nor the Technical Advisor determined that the quality of the echocardiograms prevented them from determining the level of claimant's mitral regurgitation.

12. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

We also reject claimant's assertion that she is entitled to Matrix Benefits because her eligibility echocardiogram was conducted in the Screening Program for Fund A Benefits under the Settlement Agreement. See Settlement Agreement § IV.A. The Settlement Agreement clearly provides that the sole benefit a class member is entitled to receive for a favorable echocardiogram under the Screening Program is a limited amount of medical services or a limited cash payment:

> All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to $10,000 in value to be provided by the Trust; or (ii) $6,000 in cash.

Id. § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants receiving a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with § VI.E. of the Settlement Agreement, which governs the audit of claims for

Matrix Benefits, as well as this Court's decision in PTO No. 2662, which mandated a 100% audit requirement for all claims for Matrix Benefits. See Mem. in Supp. of PTO No. 2662 at 13 (Nov. 26, 2002). As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.

Finally, to the extent claimant attempts to rely on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that she had mild mitral regurgitation, such reliance is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable where the auditing cardiologist and the Technical Advisor concluded, and claimant did not adequately dispute, that Ms. Elliott's June 19, 2001 and October 24, 2002 echocardiograms did not demonstrate even mild mitral regurgitation. Adopting claimant's argument would allow a claimant to recover benefits without meeting the requirements of the Settlement Agreement.[13]

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13. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in his

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For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had at least mild mitral regurgitation between the commencement of Diet Drug use and the end of the Screening Period. Therefore, we will affirm the Trust's denial of Ms. Elliott's claim for Matrix B-1, Level III benefits.

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13. (...continued)
statement, "An echocardiographer could not reasonably conclude that mild mitral regurgitation was present on these studies even taking into account inter-reader variability."